

Sacral neuromodulation in patients with faecal incontinence

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CHAPTER 7

Summary and General Discussion



In the present thesis, the applicability, safety and feasibility of sacral neuromodulation (SNM) as a treatment for faecal incontinence is summarized. After a decade of experience with SNM in our hospital we can conclude that SNM is an effective and in the meanwhile well-established treatment for functional bowel disorders, especially in patients with faecal incontinence.¹⁻³ The numerous international publications on the subject not only support our findings in patients with faecal incontinence but have also paved the way for SNM in the surgical treatment of faecal incontinence.⁴⁻⁶ The traditional treatment of faecal incontinence solely focusing on anal sphincter dysfunction has been abandoned and the focus has shifted towards a more complex approach.

Chapter 1 provides an overview of the literature on faecal incontinence and its treatment options. Faecal incontinence is a common but complex problem with high costs for the patient and the community. It is a psychologically devastating and socially incapacitating condition that can have profound effects on patient well being.

Adequate clinical, physiological and structural assessment through advanced imaging techniques is fundamental for assessing the cause and degree of the incontinence. Both conservative therapies (medicinal therapy, biofeedback training and colonic irrigation) and surgical interventions (sphincter repair, neosphincter formation, artificial bowel sphincter, sacral neuromodulation or formation of a stoma) are therapeutic options. However, the choice of treatment is mostly dependent on available knowledge and existing facilities.

In **Chapter 2** the outcome of our first seventy five patients treated with SNM are presented. Incontinence was objectified by completion of a 3-weeks bowel habits diary that patients also completed during ambulatory electrode stimulation at the S3 or S4 foramen. Reduction of at least 50% in incontinent episodes or days per week qualified patients for permanent implantation. Sixty six female and nine male patients were treated; the average age was 52 years (26-75). Sixty two patients (83%) had improved continence during trial screening. Median incontinence episodes per week decreased from 7.5 to 0.7 ($P < 0.01$), median incontinence days per week from 4.0 to 0.5 ($P < 0.01$). The symptomatic response remained unchanged in the fifty patients who received an implantation of a permanent electrode and neurostimulator. However, after a median follow-up of 12 months this effect could only be sustained in forty eight patients. SNM proved to be a feasible treatment option for faecal incontinence in patients with structurally intact sphincters.

In **Chapter 3** the effect of SNM on the rectum was evaluated by barostat measurements in patients with faecal incontinence who qualified for SNM. Fifteen consecutive patients were asked to undergo barostat measurements before and during sacral neuromodulation. An isobaric phasic distension protocol was used and patients were asked to report rectal filling sensations: first sensation (FS), earliest urge to defaecate (EUD) and irresistible, painful urge to defaecate (maximum tolerable volume (MTV)). Rectal wall tension and compliance could be calculated from these recordings. During stimulation median volume thresholds decreased significantly ($P < 0.01$) for FS: 98.1 vs. 44.2 ml, EUD: 132.3 vs. 82.8 ml and MTV: 205.8 vs. 162.8 ml. Pressure thresholds tended to be lower for all filling sensations and median rectal wall tensions decreased significantly ($P < 0.01$) for all filling sensations. There was no significant difference in compliance before and during stimulation. Sacral neuromodulation does affect rectal sensory perception, but it remains unclear if the success of SNM is explained solely by its effect on the rectum.

Chapter 4 describes the effect of SNM on the rectoanal angle in patients with faecal incontinence. In twelve consecutive patients who qualified for SNM a defaecography study was performed before SNM and two further studies at six months after permanent implant, one during stimulation and one with the neurostimulator off. The rectoanal angle decreased during rest, squeeze and Valsalva's manoeuvre and a slight increase in rectoanal angle was seen during defaecation. However, the differences did not reach statistical significance.

In **Chapter 5** the effect of SNM on bowel frequency and (segmental) colonic transit time is described. Fourteen consecutive patients with faecal incontinence who qualified for permanent SNM underwent a colon transit study before and one month after permanent implant. The median number of bowel movements per week decreased from 14.7(6.7-41.7) to 10.0(3.7-22.7) ($P = 0.005$) during trial screening and to 10.0(6.0-24.3) ($P = 0.008$) during permanent stimulation. No significant changes were found before and during stimulation in both segmental (right colon 6(0-25) vs. 5(0-16) hours, left colon 2(0-29) vs. 4(0-45) hours and recto sigmoid 7(28) vs. 8(0-23) hours) and total colonic transit time (17(1-65) vs. 25(0-67) hours). Although no significant change occurred in (segmental) colonic transit times a significant decrease of bowel movements was seen in patients with faecal incontinence during SNM.

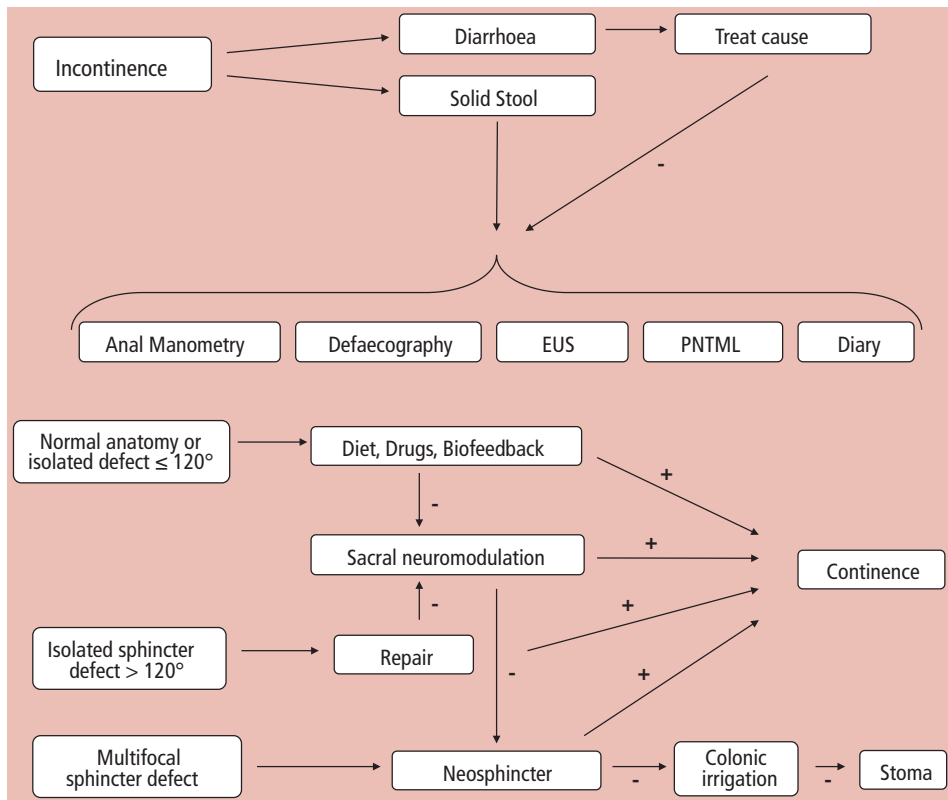
Chapter 6 evaluates the long-term outcome and quality of life in patients with faecal incontinence treated with permanent SNM. Data from our first fifty patients who qualified for permanent SNM were included in this study. A three-week bowel habits diary assessed efficacy, and the quality of life scores were obtained by the Faecal Incontinence Quality Of Life questionnaire (FIQOL) and the standard Short Form Health Survey questionnaire (SF-36). With a median follow-up of 7.1 years this is the longest reported follow-up in a substantial group of patients treated by SNM hitherto. Continence improvement of 50% or more was maintained during follow-up in forty two (84%) patients. A significant decrease in median incontinent episodes and days per week was seen during trial screening and follow-up ($P < 0.002$). Quality of life improved significantly in all four categories of the FIQOL scale and in some subscales of the SF-36 QOL questionnaire. Differences in median resting and squeeze anal canal pressures did not reach clinical significance. Although initial improvement in continence with SNM could not be maintained in all patients, with an overall success rate of 80% after permanent implant, SNM proves to be a safe and effective long-term treatment in patients with faecal incontinence.

Future perspectives and research should focus on the physiological mechanism of action and the cost effectiveness of SNM in patients with faecal incontinence. A better understanding of the physiological mechanism might not only lead to a better patient selection, but may well make the test stimulation, which currently is the only predictor available, eventually obsolete. With better understanding the application of SNM could also be broadened to other groups of patients with conditions other than FI. ⁷ SNM has already been successfully used in the treatment of patients with 'late-onset' constipation. ⁸⁻¹⁰ Patients suffering from constipation since childhood have not been studied yet. In our institution, we started a study to treat adolescent constipation patients with SNM with very good results. These results will be published in the near future. Studies reporting the effect of SNM on peri-anal pain, clitoral/pelvic pain and erectile/sexual dysfunction have been published but need further investigation. ¹¹⁻¹⁴ Furthermore, a significant reduction in diarrhea-predominant irritable bowel symptoms and improvement of quality of life was seen with percutaneous sacral nerve evaluation in patients with irritable bowel syndrome. ¹⁵ These applications of SNM for various conditions solely suggest a complex mechanism of action affecting sensory and possibly autonomic function.

The availability of functional brain imaging such as positron emission tomography (PET) and functional magnetic resonance imaging (fMRI) are intriguing possibilities. ^{16, 17} Future research using PET and fMRI should give us a better insight in both the pathophysiology of FI as well as the working mechanism of SNM.

Costs of SNM are a main concern. Although the exact costs associated with faecal incontinence are unknown the indirect or non-medical costs, such as loss of productivity, are more than half of total costs of FI.¹⁸ Several studies have already shown SNM to be cost effective in the treatment of faecal incontinence.¹⁹⁻²¹ Cost effectiveness studies will probably have to be performed in each country separately to convince local healthcare providers of the beneficial effect of SNM in patients with FI on both healthcare and society reducing the macro-economic burden. Further technical developments can also affect costs of SNM by reducing post-operative adverse events, such as infection, pain and lead migration. Stimulators with a longer life span or even rechargeable devices should lower costs further since the number of patients needing a replacement of the stimulator will grow in the future.

Clinical Pathway at the MUMC+ for Patients Presenting with Faecal Incontinence



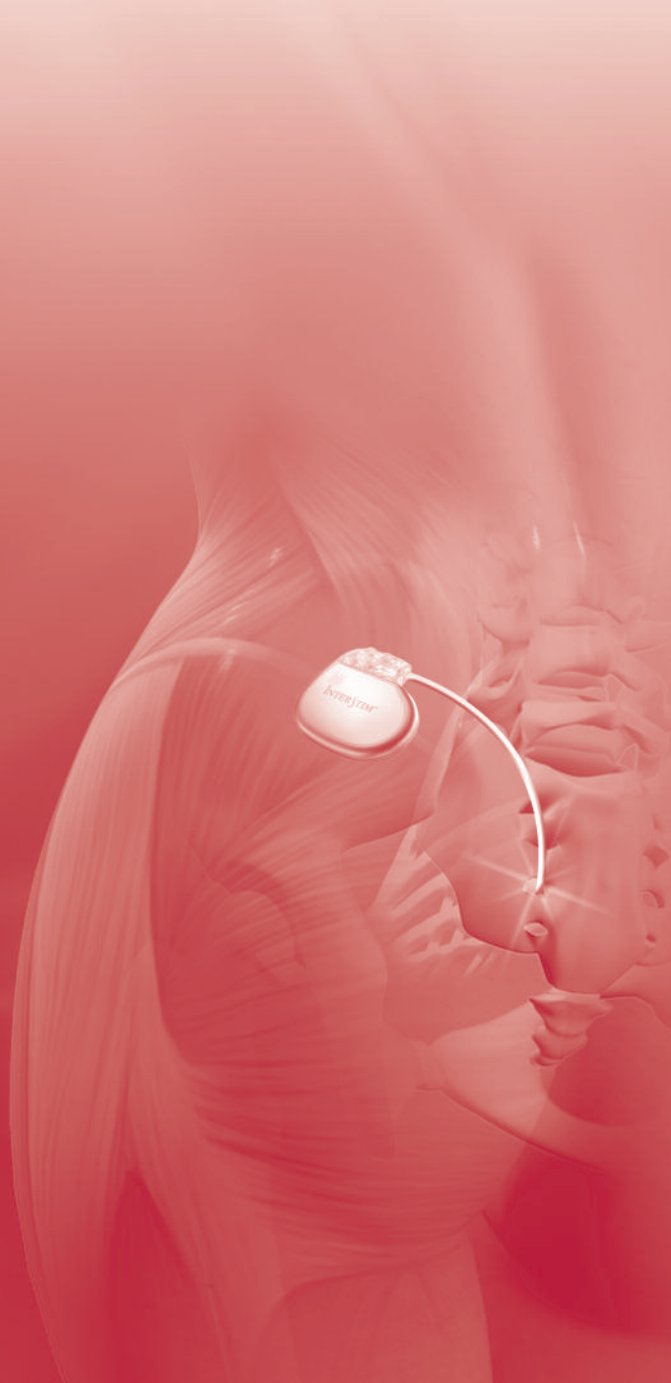
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CHAPTER 8

Samenvatting en Discussie



In dit proefschrift wordt de toepasbaarheid, veiligheid en de haalbaarheid van sacrale neuromodulatie (SNM) als behandeling voor faecale incontinentie (FI) beschreven. Na 10 jaar klinische ervaring met SNM in ons ziekenhuis kunnen we concluderen dat SNM een effectieve en in de tussentijd ook erkende behandeling is voor functionele dikkedarm klachten, met name bij patiënten met faecale incontinentie.¹⁻³ De talloze internationale publicaties bevestigen niet alleen onze bevindingen maar hebben tegelijkertijd ook de weg vrij gemaakt voor SNM in de chirurgische behandeling van patiënten met FI.⁴⁻⁶ De traditionele behandeling van FI welke zich met name concentreerde op de anale disfunctie is verlaten en is de aandacht nu verschoven naar een meer complexe benadering.

Hoofdstuk 1 geeft een overzicht van de literatuur met betrekking tot faecale incontinentie en de verschillende behandelmogelijkheden. FI is een veel voorkomende en complexe aandoening met hoge kosten voor de patiënt en de gemeenschap. Naast een grote psychische belasting heeft het een enorm sociaal invaliderend aspect dat diepgaande gevolgen heeft voor het welzijn van de patiënt. Adequate klinische, fysiologische en anatomische evaluatie door middel van onder andere geavanceerde beeldvorming is fundamenteel om de oorzaak en de mate van de incontinentie vast te stellen. Zowel conservatieve behandelingen (medicamenteus, biofeedback training en darmspoeling) als chirurgische ingrepen (sfincter herstel, neo-sfincter formatie, artificiële anale sfincter, sacrale neuromodulatie en aanleggen van een stoma) zijn therapeutische opties. De keuze voor behandeling wordt echter met name bepaald door de aanwezige kennis bij de behandelaars en de beschikbare faciliteiten.

In **Hoofdstuk 2** worden de resultaten van onze eerste vijfenzeventig patiënten die behandeld werden met SNM beschreven. Incontinentie werd geobjectiveerd door het invullen van een dagboek gedurende drie weken. Hetzelfde werd gedaan tijdens de drie weken durende proefstimulatie periode, waarbij ter hoogte van het foramen van S3 of S4 elektrisch werd gestimuleerd middels een externe stimulator. Een verbetering van de continentie van 50% of meer kwalificeerde patiënten voor een permanente implantatie. Zesenzestig vrouwelijke en negen mannelijke patiënten werden behandeld; de gemiddelde leeftijd was 52 jaar (26-75). Tweeënzestig patiënten (83%) hadden een verbeterde continentie tijdens de proefstimulatie. Het aantal incontinente episoden per week daalde van mediaan 7.5 naar 0.7 ($P < 0.01$), en het aantal incontinente dagen per week van mediaan 4.0 naar 0.5 ($P < 0.01$). De symptomatische verbetering bleek reproduceerbaar in de vijftig patiënten bij wie

een permanente elektrode en neurostimulator geïmplanteerd werd. Na een mediane follow-up van 12 maanden bleef dit effect slechts gehandhaafd in achtenveertig patiënten. SNM bleek een toepasbare behandeling voor faecale incontinentie bij patiënten met een intacte sfincter.

In **Hoofdstuk 3** wordt het effect van SNM op het rectum geëvalueerd door middel van barostat metingen bij patiënten met faecale incontinentie die werden behandeld middels SNM. Bij vijftien achtereenvolgende patiënten werden barostat metingen verricht vóór en tijdens permanente SNM. Een isobaar fasisch distensie protocol werd gebruikt en aan de patiënten werd gevraagd rectale vulling sensaties aan te geven: eerste sensatie (ES), eerste aandrang tot defaecatie (EAD) en onweerstaanbare/pijnlijke aandrang tot defaecatie (maximum tolereerbaar volume (MTV)). De rectale wandspanning en compliantie konden met deze metingen worden berekend. Tijdens stimulatie daalden de mediane volumes significant ($P < 0.01$) voor ES: 98.1 vs. 44.2 ml, EAD: 132.3 vs. 82.8 ml and MTV: 205.8 vs. 162.8 ml. De druk metingen neigden lager uit te vallen voor alle vullingsensaties en de rectale wandspanning daalde significant ($P < 0.01$) bij alle vullingsensaties. Er was geen significant verschil in compliantie voor en tijdens SNM. Sacrale neuromodulatie beïnvloedt dus de rectale viscerale sensitiviteit maar het blijft onduidelijk of dit effect alléén het succes van SNM kan verklaren.

Hoofdstuk 4 beschrijft het effect van SNM op de anorectale hoek bij patiënten met faecale incontinentie. Bij twaalf achtereenvolgende patiënten die in aanmerking kwamen voor SNM werden een defaecografie studie vóór SNM en twee defaecografie studies 6 maanden na implantatie vericht, één tijdens stimulatie en de ander met de neurostimulator uit. De anorectale hoek werd kleiner tijdens rust, knijpen en Valsalva's manoeuvre en er werd een lichte toename van de anorectale hoek gezien tijdens defaecatie. De verschillen bereikten echter geen statistische significantie.

In **Hoofdstuk 5** wordt het effect van SNM op de defaecatiefrequentie en (segmentele) colon transitijd onderzocht. Veertien achtereenvolgende patiënten met faecale incontinentie die behandeld werden middels SNM ondergingen een colontransit studie vóór de SNM behandeling en één maand na permanente neurostimulator implantatie. Het aantal defaecatiemomenten per week daalde van mediaan 14.7(6.7-41.7) naar 10.0(3.7-22.7) ($P = 0.005$) tijdens proefstimulatie en naar mediaan 10.0(6.0-24.3) ($P = 0.008$) tijdens permanente stimulatie. Er werden

geen significante verschillen gevonden vóór en tijdens stimulatie in zowel segmentele (rechter colon 6(0-25) vs. 5(0-16) uren, linker colon 2(0-29) vs. 4(0-45) uren en rectosigmoïd 7(28) vs. 8(0-23) uren) als totale colon transittijd (17(1-65) vs. 25(0-67) uren). Alhoewel er geen significante verschillen werden gevonden in (segmentele) colon transittijd werd er wel een significante vermindering gezien in het aantal defaecatie momenten bij patiënten met faecale incontinentie tijdens SNM.

Hoofdstuk 6 evalueert de lange termijn resultaten en kwaliteit van leven bij patiënten met faecale incontinentie die behandeld werden met permanente SNM. De data van onze eerste vijftig patiënten die in aanmerking kwamen voor een permanente stimulatie werden gebruikt in deze studie. Patiënten hielden een defaecatiedagboek bij en de kwaliteit van leven scores werden verkregen middels de Faecal Incontinence Quality of Life vragenlijst (FIQOL) en de standard Short Form Health Survey vragenlijst (SF-36). Met een mediane follow-up van 7.1 jaar is dit de langste follow-up tot nu toe beschreven in een aanzienlijke groep patiënten die behandeld zijn met SNM. Tijdens follow-up kon in 42 (84%) patiënten de continentie verbetering van 50% of meer worden gehandhaafd. Er werd een significante afname van incontinentie episoden en dagen per week gezien tijdens proefstimulatie en follow-up na permanente stimulatie ($P < 0.002$). Kwaliteit van leven verbeterde significant in alle vier categorieën van de FIQOL schaal en in enkele categorieën van de SF-36 vragenlijst. Verschillen in mediane anale rust- en knijpdrukken bereikten geen klinische significantie. Alhoewel het initiële succes niet gehandhaafd kon blijven in alle patiënten, blijkt permanente SNM met een overall succespercentage van 80% een veilige en effectieve lange termijn behandeling voor patiënten met faecale incontinentie.

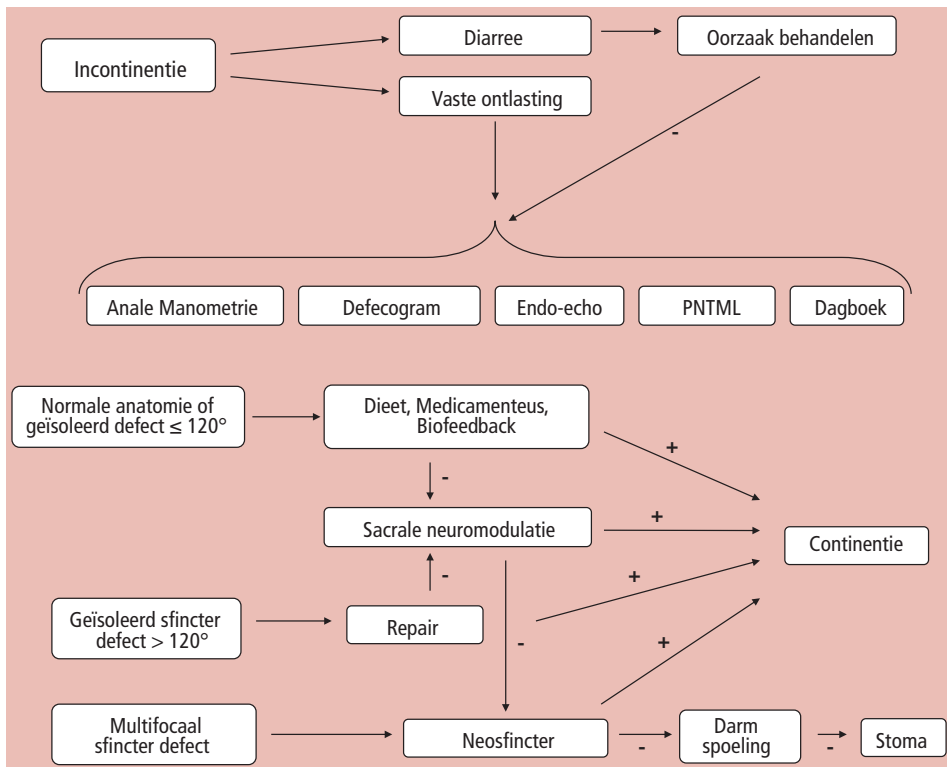
Toekomstige perspectieven. Verder onderzoek zal zich moeten richten op het fysiologisch werkingsmechanisme en de kosteneffectiviteit van SNM bij patiënten met faecale incontinentie. Een beter begrip van het fysiologisch mechanisme zou kunnen leiden tot een betere patiëntselectie en zou eventueel zelfs de proefstimulatie, welke op het moment de enige voorspellende factor is, uiteindelijk overbodig kunnen maken. Met een beter begrip zou ook de toepassing van SNM verbreed kunnen worden naar groepen patiënten met een andere aandoening dan faecale incontinentie.⁷ SNM is al succesvol gebruikt in de behandeling van patiënten met therapie resistente obstipatie die op latere leeftijd is ontstaan.⁸⁻¹⁰ Patiënten met obstipatie klachten sinds de kinderleeftijd zijn nog niet onderzocht. In ons ziekenhuis zij we gestart met een studie waarbij adolescenten met obstipatie

worden behandeld middels SNM. De eerste resultaten lijken veelbelovend en zullen binnenkort worden gepubliceerd. Effecten van SNM op peri-anale pijn, clitorale/bekken pijn en erectiele/sexuele disfunctie zijn reeds beschreven maar moeten nader onderzocht worden.¹¹⁻¹⁴ Een significante reductie van symptomen en verbetering van kwaliteit van leven werd gezien tijdens proefstimulatie bij een subgroep patiënten met prikkelbare darm syndroom bij wie diarree het belangrijkste symptoom was.¹⁵ Deze verschillende toepassingen van SNM alléén al suggereren een complex mechanisme waarbij sensorische en mogelijk autonome functies beïnvloed worden.

De beschikbaarheid van functionele beeldvorming van de hersenen zoals positron emissie tomografie (PET) en functionele magnetische resonantie imaging (fMRI) zijn interessante mogelijkheden.^{16, 17} Toekomstig onderzoek met PET en fMRI kunnen ons een beter inzicht geven in zowel de pathofysiologie van faecale incontinentie als het werkingsmechanisme van SNM.

De kosten van SNM zijn een grote zorg. Alhoewel de exacte kosten geassocieerd met faecale incontinentie onbekend zijn blijken de indirecte non-medische kosten, zoals verminderde productiviteit van de patiënt op de arbeidsmarkt, meer dan de helft te zijn van de totale kosten van FI.¹⁸ Meerdere studies hebben reeds de kosten effectiviteit van SNM bij de behandeling van faecale incontinentie aangetoond.¹⁹⁻²¹ Kosteneffectiviteit studies zullen hoogstwaarschijnlijk in elk land apart uitgevoerd moeten worden om lokale zorgverleners te overtuigen van het positieve effect van SNM bij patiënten met FI op zowel de gezondheidszorg als de gemeenschap door het reduceren van de macro-economische last. Toekomstige technische ontwikkelingen kunnen de kosten van SNM beïnvloeden door bijvoorbeeld het verminderen van postoperatieve complicaties zoals infecties, pijn en elektrodemigratie. Door de ontwikkeling van neurostimulatoren die langer meegaan of zelfs opgeladen kunnen worden zullen kosten verder moeten dalen aangezien het aantal patiënten dat toekomt aan een vervanging van de neurostimulator in de toekomst alleen maar zal toenemen.

Behandel Stroomdiagram in het MUMC⁺ voor Patiënten met Faecale Incontinentie



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CHAPTER 9

Sonuçlar ve Tartışma



SONUÇLAR VE TARTIŞMA

Bu tezde, fekal inkontinans tedavisi için sakral nöromodülasyon (SNM) uygulamasının fizibilitesi, uygulanabilirliği ve güvenilirliği özetlenmiştir. Hastanemizde SNM ile 10 yıllık klinik deneyim sonrasında sonuçlarımız SNM in fonksiyonel bağırsak şikayetlerinde, özellikle fekal inkontinans hastalarında, etkin ve bu arada kanıtlanmış bir yöntem olmasıdır.¹⁻³ Konuyla ilgili çok sayıdaki uluslararası yayınlar sadece bulguları doğrulamakla değil aynı zamanda fekal inkontinans hastalarının cerrahi tedavisinde SNM'in uygulanabilir olması yolunu açtı.⁴⁻⁶ Geleneksel fekal inkontinans tedavisinde özellikle anal disfonksiyonu üzerine odaklanması terkedildi ve ilgi daha kompleks bir yaklaşıma yöneltildi.

Bölüm 1 fekal inkontinans ile ilgili edebiyat özetini ve farklı tedavi seçeneklerini gösterir. Fekal inkontinans yaygın ve kompleks bir hastalık olmasının yanı sıra hastalar ve toplum için yüksek maliyeti olan bir hastalıktır. Büyük psikolojik stresin yanısıra hastanın sosyal hayatına derin negatif etkileri vardır. Inkontinans derecesini ve sebebini belirlemek için uygun klinik, fizyolojik ve anatomik değerlendirme önemlidir. Hem konservatif (ilaç, biofeedback terapisi ve kolon irrigationu) hem de cerrahi tedaviler (sfinkter onarımı, neo-sfinkter oluşumu, yapay anal sfinkter, sakral nöromodülasyon ve stoma oluşturma) terapötik seçeneklerdir. Tedavi seçimi ancak mevcut olan bilgi ve imkanlar sonucunda belirlenir.

Bölüm 2'de SNM ile tedavi edilen ilk yetmiş beş hastanın sonuçları açıklanmaktadır. Inkontinans üç hafta boyunca bir günlük tutularak somutlaştırıldı. Stimülasyon testi döneminde, aynı şekilde üç haftalık günlük tutulmuştur. Inkontinans %50 veya daha fazla bir gelişme hastaya kalıcı implantasyon uygulanması için kriter kabul edildi. Altmış altı kadın ve dokuz erkek hasta tedavi edildi; yaş ortalaması 52 (dağılım 26-75). Altmış iki hastada (%83) test stimülasyonu sırasında kontinansın iyileştiği tespit edildi. Haftalık inkontinans dönemleri ortalama olarak 7.5 tan 0.7'e düşmüştür ($P < 0.01$), inkontinans gün sayısı ortalama 4.0 dan 0.5'e düşmüştür ($P < 0.01$). Semptomatik yanıt kalıcı bir elektrot ve pacemaker implante edilen elli hastada değişmedi. Bu etki 12 aylık medyan takip sonrası sadece kırk sekiz hastada muhafaza edilebildi. SNM bozulmamış sfinkter hastalarında fekal inkontinans için uygulanabilir bir tedavi olarak kanıtlandı.

Bölüm 3 te SNM'in, fekal inkontinans için SNM ile tedavisi kabul edilen hastalarda, barostat ölçümleri vasıtasıyla rektuma olan etkisi değerlendirildi. On beş ardışık hasta üzerinde SNM öncesi ve sonrası barostat ölçümleri yapıldı. İzobarik fazik distansiyon protokolü kullanıldı ve hastalara rektal dolum hislerini belirtmeleri istendi: birinci his (BH), ilk dışkılama dürtüsü (IDD) ve dayanılmaz/ağrılı dışkılama dürtüsü (maksimum tolere hacmi (MTH)). Rektal duvar gerilimi ve rektal komplians bu ölçümlerle hesaplandı. Stimülasyon esnasında ortalama hacim ölçümleri anlamlı ölçüde azaldı ($P < 0.01$); BH: 98.1 vs 44.2 ml, IDD: 132.3 vs 82.8 ml, MTH: 205.8 vs 162.8 ml. Basınç ölçümlerinde tüm rektal dolum duyumlarında azalma görüldü. Rektal duvar geriliminde, tüm dolum duyumlarında, anlamlı ölçüde ($P < 0.01$) azalma tespit edilmiştir. SNM öncesi ve sonrası rektal komplians anlamlı ölçüde bir değişiklik tespit edilmemiştir. SNM rektal visseral duyarlılığı etkiler ama bu etkinin tek başına SNM başarısını açıklayabileceği belirsizdir.

Bölüm 4 te fekal inkontinansı olan hastalarda SNM'in anorektal açığa olan etkisi açıklanmaktadır. SNM ile tedavi için nitelendirilmiş oniki ardışık hasta üzerinde defecografi çalışması yapılmıştır. SNM öncesi bir çalışma ve 6 ay SNM sonrası, biri stimülasyon sırasında ve diğeri neurostimülatör kapalı iken, iki çalışma düzenlenmiştir. Anorektal açığı istirahat, sıkma ve Valsalva's manevrası esnasında küçüldü ve dışkılama sırasında anorektal açığı hafif bir artış gösterdi. Ancak farklılıklar istatistiksel olarak anlamlı ölçüde bir değişiklik göstermedi.

Bölüm 5'te SNM'in dışkılama sıklığı ve segmental kolonik transit zamanına etkisi araştırılmıştır. SNM ile tedavi gören on dört ardışık fekal inkontinans hastalarında, SNM öncesi ve kalıcı implantasyondan bir ay sonra, kolon transit çalışması yapıldı. Haftalık dışkılama sayısında, stimülasyon testi esnasında ortalama 14.7'den (6.7-41.7) 10.0'a (3.7-22.7) ($P = 0.005$), kalıcı stimülasyon esnasında ortalama 10.0'a kadar (6.0-24.3) ($P = 0.008$) azalma görüldü. Stimülasyon öncesi ve sonrası her ikisinde, segmental (sağ kolon 6 (0-25) vs 5. (0-16) saat, sol kolon 2 (0-29) vs. 4 (0-45) saat ve rektosigmoid 7(28) 8 (0-23) saat) ve total kolonik transit zamanında (vs 17 (1-65) vs. 25 (0-67) saat), anlamlı ölçüde değişiklikler bulunmadı. Segmental kolonik transit zamanında anlamlı ölçüde farklılık bulunmamasına rağmen, SNM esnasında fekal inkontinans hastalarında defekasyon sayısında anlamlı ölçüde azalma tespit edilmiştir.

Bölüm 6 uzun vadeli sonuçları ve kalıcı SNM ile tedavi edilen fekal inkontinans hastalarının yaşam kalitesini değerlendirir. Kalıcı stimülasyon için tedavi gören ilk elli hastanın verileri bu çalışmada kullanıldı. Hastalar defekasyon günlüğü tuttular ve yaşam kalitesi skoru Faecal Incontinence Quality Of Life anketi (FIQOL) ve standart Short Form Health Survey anketi (SF-36) ile elde edildi. Ortalama 7.1 yıllık izlem ile bu araştırma, şimdiye kadar SNM ile tedavi edilen büyük bir grup hastada, yapılan en uzun izlem çalışmasıdır. İzlem esnasında 42 (%84) hastada %50 veya daha fazla kontinans iyileşmesi elde edilmiştir. Stimülasyon esnasında ve kalıcı stimülasyon sonrası izleminde inkontinans dönemlerinde ve günlerinde anlamlı ölçüde azalma tespit edilmiştir ($P < 0.002$). Yaşam kalitesi, FIQOL ölçeğinin dört kategorisinde ve SF-36 anketinin bir kaç kategorisinde, anlamlı ölçüde iyileşme göstermiştir. Ortalama anal istirahat ve sıkma basınçları arasındaki farkta anlamlı ölçüde bir değişiklik tespit edilmedi. İlk başarı tüm hastalarda muhafaza olmamasına rağmen, kalıcı SNM'in fekal inkontinans hastalarında %80 genel bir başarı oranı ile güvenli ve etkili uzun süreli bir tedavi şekli olduğu kanıtlanmıştır.

Gelecek perspektifler ve araştırmalar, fizyolojik mekanizma ve fekal inkontinansı olan hastalarda SNM'in maliyet etkinliği üzerinde odaklanmalıdır. Fizyolojik mekanizmaların daha iyi anlaşılması doğru hasta seçimine neden olabilir ve hatta test stimülasyonunu neticede gereksiz kılar. Aynı zamanda daha iyi bir anlayış ile SNM tedavisi sadece fekal inkontinansı olan hastalarda değil diğer rahatsızlıkları olan hastalarda uygulanabilir. ⁷ SNM tedavisi zaten, ileri yaşlarda ilaç dirençli kabızlık rahatsızlığı gören hastalarda, başarıyla uygulanmıştır. ⁸⁻¹⁰ Çocukluk döneminden itibaren kabızlık rahatsızlığı olan hastalar henüz araştırılmamıştır. Biz kabızlık rahatsızlığı gören ergenlere SNM tedavisi uygulamaya başladık ve iyi sonuçlar elde ettik. Sonuçlar kısa sürede yayınlanacaktır. SNM'in peri anal ağrıya, klitoral/pelvik ağrıya ve erektel/cinsel işlev bozukluğuna etkileri zaten tarif edilmiştir ancak daha fazla araştırılması gerekmektedir. ¹¹⁻¹⁴ Stimülasyon testi sırasında, ishal baskın irritabil barsak sendromu hastalarında, belirtilerde ve yaşam kalitesi iyileşmesinde anlamlı ölçüde azalma tespit edilmiştir. ¹⁵ Sadece bu farklı kullanımlar bile SNM in duyuşal ve otonomik fonksiyonları içeren karmaşık bir mekanizmayı etkilediğini düşündürmektedir.

Beynin fonksiyonel görüntüleme durumunu gösteren cihazlar, pozitron emisyon tomografisi (PET) ve fonksiyonel manyetik rezonans görüntüleme (fMRI), ilginç olanaklardır. ^{16, 17} PET ve fMRI ile ileri çalışmalar SNM'in etki mekanizmasını ve fekal inkontinansın patofizyolojisi hakkında daha iyi bir fikir verebilir.

SNM'in maliyeti büyük bir endişedir. Fekal inkontinans ile ilgili maliyet kesin olmasada, dolaylı tıbbi olmayan maliyetler (verimlilik gibi) toplam maliyetin yarısından fazlasını kapsamaktadır.¹⁸ Çeşitli çalışmalar SNM'in fekal inkontinans tedavisinin maliyetini ve etkinliğini zaten belirtmiştir.¹⁹⁻²¹ Yerel sağlık hizmetlerini SNM'in fekal inkontinans hastalarında olumlu etkilerini (sağlık hizmetleri vede toplum için makro-ekonomik yükü azaltarak) inandirmek için muhtemelen ayrı ayrı ülkelerde maliyet çalışmaları yapılmalıdır. Gelecek teknik gelişmeler örneğin ameliyat sonrası komplikasyonlarını (enfeksiyon, ağrı ve elektrot göçü) etkileyebilir ve bu yüzden SNM'in toplam maliyetini azaltabilir. Gelecekte neurostimülatörü değiştirilmesi gereken hasta sayısı artacaktır. Bunu göz önüne alırsak daha uzun ömürlü ve hatta şarj edilebilir neurostimülatörlerin geliştirilmesi ile SNM'in maliyeti düşmeye devam etmesi gerekir.

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